K002919
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510(k) SUMMARY

Submitter's Name:	American Medical Systems, Inc.
Address:	10700 Bren Road West Minnetonka, MN 55343
Tel:	952-933-4666
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Contact Person:	Elsa A. Linke
Date of Summary Preparation:	September 15, 2000
Device Common Name:	Artificial Urinary Sphincter
Device Trade Name:	AMS Sphincter 800™ Urinary Prosthesis
Device Classification Name:	Implanted Mechanical/Hydraulic Urinary Continence Device (21 CFR 876.5280)
Predicate Device:	Implanted Mechanical/Hydraulic Urinary Continence Device (21 CFR 876.5280)

Device Description

The AMS Sphincter 800™ Urinary Prosthesis consists of three interconnected components: control pump, pressure regulating balloon and occlusive cuff. The pump is implanted in the subcutaneous tissue of the scrotum or labia. The pressure regulating balloon is implanted in the prevesical space. The occlusive cuff is implanted around the bulbous urethra or bladder neck. Kink resistant tubing connects these three components together.

In operation, the urethra is closed by gentle occlusion when the implanted cuff is filled with prosthesis fluid. Pressing the control pump moves fluid from the cuff into the balloon. This action restores urethral patency and allows the patient to void. Once pumping ceases, fluid returns slowly back into the occlusive cuff from the balloon, which restores urinary continence.

Indications for Use

The AMS Sphincter 800™ Urinary Prosthesis is an implantable, fluid-filled, solid silicone elastomer device used to treat urinary incontinence caused by Intrinsic Sphincter Deficiency (ISD). The AMS Sphincter 800™ Urinary Prosthesis is implanted in men, women and children.

Comparison to Predicate Device

The fundamental scientific technology of the device will not change with the proposed alternative configuration of the device. The physical characteristics of all components

remain the same. A three-way connector, made of the same material as the other connectors currently used, is now packaged with the device.

Supporting Information

A risk analysis of the proposed modification and bench test data reported in this 510(k) application substantiate equivalence to the predicate and did not raise any new questions of safety or effectiveness.

Conclusion

The proposed modification is equivalent to the predicate with respect to intended use, technological characteristics, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2000

Ms. Elsa A. Linke
Regulatory Affairs Associate
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343

Re: K002919
AMS Sphincter 800™ Urinary Prosthesis
Dated: September 18, 2000
Received: September 19, 2000
Regulatory Class: III
21 CFR §876.5280/Procode: 78 EZY

Dear Ms. Linke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE ENCLOSURE

510(k) Number: K002919

Device Name: AMS Sphincter 800™ Urinary Prosthesis

Indications for Use: The AMS Sphincter 800™ Urinary Prosthesis is an implantable, fluid-filled, solid silicone elastomer device used to treat urinary incontinence caused by Intrinsic Sphincter Deficiency (ISD). The AMS Sphincter 800™ Urinary Prosthesis is implanted in men, women and children.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002919